DialyzeDirect

December 20, 2017

Physician-Focused Payment Model Technical Advisory Committee
C/o U.S. DHHS Asst. Secretary for Planning and Evaluation Office of Health Policy
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Letter of Intent – Dialyze Direct's Proposed APM for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities

Dear Committee Members,

Dialyze Direct is an End-Stage Renal Disease ("ESRD") training and support facility located in Florida, Texas, New York, New Jersey, and Pennsylvania. Dialyze Direct's home hemodialysis program is a patient-centric model designed for geriatric patients residing in skilled nursing facilities ("SNFs") that achieves optimal patient outcomes by providing point of care hemodialysis services technically modified for the geriatric population, while significantly reducing costs. We are writing to indicate our intent to submit a Physician Focused Payment Model ("PFPM") for PTAC review on or about January 1, 2018, as briefly described below.

Payment Model Overview

The PFPM will utilize a bundled pricing model for Medicare geriatric ESRD patients residing in SNFs and are receiving home hemodialysis by Dialyze Direct. The bundled payment will encompass all payments for a home hemodialysis treatment, including drugs, laboratory services, supplies, equipment, transportation, home and self-dialysis training, support services necessary for the effective performance of a patent's dialysis furnished in the ESRD facility or in a patient's home, and other capital-related costs associated with furnishing maintenance dialysis services. Further, the bundled pricing model will save a significant amount of financial resources through the redistribution of funds to the proposed model.

We believe the proposed model will meet the MACRA requirements for an Advanced Alternative Payment Model because Dialyze Direct uses certified EHR technology, bases payment on quality measures comparable to the quality performance category of the Merit-based Incentive Payment System ("MIPS"), and will bear more than a nominal financial risk through the program. Because of the frailty and complexity of the co-morbidities surrounding the geriatric dialysis population, we believe that a unique and patient-centric delivery and therapy model is necessary in order to address the clinical and financial issues associated with the geriatric dialysis population.

Goals of the Model

Expected results of the model will include significant improvements in medical outcomes, enhanced patient experience and quality of life, and a reduction in payer spending for cost of care. Improved medical outcomes include but are not limited to improved fluid management, improved blood pressure control and prevention and/or regression of left ventricular hypertrophy, reduction in frequency of intradialytic falls in blood pressure and the consequent organ damage, reduction in number and frequency of medications, reduction in permcath-related infections including bacteremia, and reduction in post-hemodialysis recovery time. A particular emphasis will

be placed on on-site coordination of care with the SNF that is unachievable when a SNF dialysis patient is being transferred to and from a remote dialysis facility three (3) times a week. Enhanced patient experience and quality of life include eliminating strenuous and potentially dangerous transportation to and from dialysis facilities, missed rehabilitation sessions, missed meals, and missed social events. Lastly, a reduction in payer spending will result from the total elimination of transportation from a SNF to a dialysis facility, reductions or elimination of a number of medications, and a decrease in hospitalizations and re-hospitalizations as a result of the improved medical outcomes listed above.

Expected Participants

The model will focus on geriatric dialysis patients residing in SNFs who have elected to receive home hemodialysis services provided by Dialyze Direct. Nephrologists have a significant role in geriatric dialysis patients lives because dialysis is the life support of an ESRD patient, and their decisions in the care for geriatric dialysis patients have a significant correlation in patient outcomes and payer costs. Therefore, we expect participants to include nephrologists and nephrology groups.

Implementation Strategy

Dialyze Direct operates ESRD training and support facilities in Florida, Texas, New Jersey, New York, and Pennsylvania, and have dialyzed over 300 patients to date. Dialyze Direct's model focuses on staff-assisted, home hemodialysis care for geriatric dialysis patients who reside in SNFs and require chronic intermittent dialysis services to survive. Dialyze Direct provides care on-site at the SNF in a communal "home dialysis room" where Dialyze Direct's trained caregivers provide point-of-care services to patients under the direct oversight of a Dialyze Direct home dialysis registered nurse. By repurposing NxStage Medical, Inc's five (5) times per week dialysis technology, originally developed for younger patients performing dialysis in their home, Dialyze Direct customized a slower, more gentle and effective fluid removal protocol for the geriatric SNF dialysis populations. Dialyze Direct's on-site dialysis staff works closely with the SNF staff in order to achieve optimal coordination of care that results in improved patient outcomes and reduces payer costs.

Timeline

Dialyze Direct expects to submit the proposal March 1, 2018. If approved, Dialyze Direct will be prepared to implement the payment model in Q2 of the 2018 calendar year.

We thank you for your consideration and look forward to submitting our full proposal.

Respectfully submitted,

Nathan Levin, M.D.
Chairman, Medical Advisory Board

Allen Kaufman, M.D.
Chief Medical Officer, Senior Vice-President,
Clinical & Scientific Affairs